

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

§ 507.31 Food safety plan.

(a) You must prepare, or have prepared, and implement a written food safety plan.

(b) One or more preventive controls qualified individuals must prepare, or oversee the preparation of, the food safety plan.

(c) The written food safety plan must include:

(1) The written hazard analysis as required by § 507.33(a)(2);

(2) The written preventive controls as required by § 507.34(b);

(3) The written supply-chain program as required by subpart E of this part;

(4) The written recall plan as required by § 507.38(a)(1);

(5) The written procedures for monitoring the implementation of the preventive controls as required by § 507.40(a)(1);

(6) The written corrective action procedures as required by § 507.42(a)(1); and

(7) The written verification procedures as required by § 507.49(b).

(d) The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.

§ 507.33 Hazard analysis.

(a)(1) You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control; and

(2) The hazard analysis must be written regardless of its outcome.

(b) The hazard identification must consider:

(1) Known or reasonably foreseeable hazards that include:

(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;

(ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food

or color additives, and nutrient deficiencies or toxicities (such as inadequate thiamine in cat food, excessive vitamin D in dog food, and excessive copper in food for sheep); and

(iii) Physical hazards (such as stones, glass, and metal fragments); and

(2) Known or reasonably foreseeable hazards that may be present in the animal food for any of the following reasons:

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced; or

(iii) The hazard may be intentionally introduced for purposes of economic gain.

(c)(1) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

(2) The hazard evaluation required by paragraph (c)(1) of this section must include an evaluation of environmental pathogens whenever an animal food is exposed to the environment prior to packaging and the packaged animal food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

(d) The hazard evaluation must consider the effect of the following on the safety of the finished animal food for the intended animal:

(1) The formulation of the animal food;

(2) The condition, function, and design of the facility and equipment;

(3) Raw materials and other ingredients;

(4) Transportation practices;

(5) Manufacturing/processing procedures;

(6) Packaging activities and labeling activities;

(7) Storage and distribution;

(8) Intended or reasonably foreseeable use;

(9) Sanitation, including employee hygiene; and

(10) Any other relevant factors such as the temporal (*e.g.*, weather-related)